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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/085,271	05/26/98	MARTIN	W	234/293

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EXAMINER	
YUCEL, I	

ART UNIT	PAPER NUMBER
1636	2

DATE MAILED: 09/01/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

please see attached

☆U.S.GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary	Application No. 09/085,271	Applicant(s) Martin
	Examiner Remy Yucel	Group Art Unit 1636

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-25* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-25* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-25 are pending in the application.

Priority/Oath/Declaration

Applicant indicates that this application is a CIP and claims benefit of application serial numbers 07/887,502, filed 22 May 1992 and was abandoned 11 December 1993. The instant application was filed 26 May 1998, clearly these two applications were not copending at the time the instant application was filed. It appears that there are other applications in the parentage of the instant application that fail to appear on the oath/declaration and in the first sentence of the disclosure. Reference to all of the parent applications and the status of these applications in the first sentence of the specification is required. A new oath or declaration reciting the complete list of prior applications and their relationship to the instant application is required for Applicant to have benefit of the earliest filing date of 20 September 1991 for application serial number 07/763,039.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,756,281. The conflicting claims drawn to methods are not identical because they differ in their preambles; however, the methods are not patentably distinct from each other because they recite the same steps. Thus, it would have been obvious to the ordinary artisan that the patented methods for detecting a cytopathic effect caused by a stealth virus would also be used for methods of detecting and methods of culturing a stealth virus because the instant methods and the patented methods comprise the same steps and rely on inoculating a permissive cell line and detecting a cytopathic effect in the cells.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-6 and 13-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Martin (A).

The instant claims are drawn to methods of detecting and culturing a stealth virus involving culturing samples or permissive cell lines inoculated with stealth virus-containing samples and detecting cytopathic effects (CPE) in the permissive cell line such as *Spodoptera fruiperda* ovarian cell line Sf9. Some of the methods comprise steps in which the culture medium is replaced every 24 to 72 hours, while other methods call for the use of specific serum-free media. Other methods involve the use of supernatants from cells infected with other viruses as virus-enhancing media (VEM).

Martin (A) discloses methods for detecting and culturing stealth viruses. He teaches the use of serum-free media (specifically X Vivo-15 or medium 199) in the disclosed culture and detection methods. Martin teaches a variety of permissive cell lines including the *Spodoptera fruiperda* ovarian cell line Sf9. He also teaches the use of VEM obtained from "supernatants of actively replicating viruses" such as CMV and herpesvirus-6. Martin discloses replacing the culture medium every 24 to 72 hours for the detection of CPE. Thus, Martin teaches all that is recited in the instant claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

§ 2172.01. The claim is drawn to a method of detecting a stealth virus; however the method appears to be missing one or more steps, including a step in which the stealth virus is detected.

Claims 7-25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. These claims are drawn to methods of culturing a stealth virus; however they appear to be missing at least one step which relates to or reiterates the preamble. For example, claim 7 is drawn to a method of culturing a stealth virus, but the last step of the process is detection of a cytopathic effect.

Claims 6, 11, 12 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims contain the recitation "derived", however this recitation renders the claims indefinite because it is not clear what derivation processes are encompassed by the this term. The word "derived" in the instant claims is taken to mean "obtained" for examination purposes. However, the word has another meaning in art; to produce or obtain from another substance by chemical reaction. Thus, it is not clear what derivative processes are envisioned by Applicant. It is suggested that "isolated" or "obtained" be used instead for clarity of the claims.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

The claim is drawn to a method for culturing a stealth virus, however, there is no nexus between the sample used to inoculate the permissive cell line and stealth viruses.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is encompassed by the term "environmental substance". Thus the metes and bounds of the claim are not defined.

Claim 14 refers to "the serum-free medium" in the method of claim 12, however, there is insufficient antecedent basis for this term in claim 12.

Claim 20 refers to "said viral enhancing medium" in the method of claim 18 which depends from claim 14, which depends from claim 12, which depends from claim 7. None of the preceding claims provides antecedent basis for this term.

Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims depend from claims 21 and 23, respectively which ultimately depend from claim 7. Claim 7 is drawn to a method of culturing stealth viruses, which by the definition presented at least at page 3, excludes cytomegalovirus and herpesvirus-6 since a stealth virus-infected cells cannot react with typing sera specific for cytomegalovirus and herpesvirus-6 nor cannot hybridize with specific probes to these viruses. Thus, it is not clear how cytomegalovirus or herpesvirus-6 can be the "said virus" in claim 7.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6 (d)). The Group 1800 FAX numbers are (703) 308-4242 or (703) 305-3014. Unofficial faxes may be sent to the examiner at (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irem Yucel, Ph. D. whose telephone number is (703) 305-1998. The examiner can normally be reached on Monday through alternate Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Remy Yucel, Ph. D.
August 27, 1998

JAMES KETTER
PRIMARY EXAMINER